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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,324	12/08/99	CICHUTEK K	10383/006001

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J PETER FASSE
FISH & RICHARDSON
225 FRANKLIN STREET
BOSTON MA 02110-2804

EXAMINER	
BRUNOVSKIS,P	
ART UNIT	**PAPER NUMBER**
1632	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/380,324	Applicant(s) Cichutek And Stitz
	Examiner Peter Brunovskis	Group Art Unit 1632

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☒ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: *19808438.2*.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on Application No. 19808438.2 filed in Fed. Rep. Germany on 2/27/98. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Claim Objections

Claim 1-8 are objected to because of the following informalities:

The beginning of each claim employing the terms "Retroviral vectors" (claims 1-3), "Method" (claims 4-7), and "Packaging cells" (claim 8) should conform to proper English usage being preceded by --A-- in independent claims or --The-- in dependent claims.

In claim 4, use of hyphens in "gag-, pol- and expression construct-positive" implies that the packaging cell is gag-negative and poly negative. Changing claim to --gag-positive, pol-positive-- or --gag+, pol+, expression construct+-- would obviate the problem. Also, "env-positive" should be deleted since there is inconsistency between the use of "(gag-, pol- and expression construct-positive)" in referring to a type of packaging cell and in using "(env-positive)" in the other case to refer to "an expression-gene".

Claims 4, 5, and 7 are objected to for their recitation of "expression-gene(s)" (cl. 4, line 4; cl. 5, lines 2 and 4; cl. 7, line) which is not a proper art-recognized term. This recitation is

inconsistent with the limitations of claim 7 wherein multi-gene constructs are used and there is no definition of "expression gene" in the specification. The term "expression gene" should be deleted or modified.

Claims 4 and 5 are also objected to for their recitation of "expression construct" (cl. 4, line 3; cl. 5, line 3). A better phrase would be "packaging construct encoding a transgene". "Expression construct" would be a more appropriate term for "expression gene" above.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) is rendered indefinite by its multiple use of "and" and "or" and lack of punctuation since it is not clear which limitations apply to different sets of terms or phrases. For example, it is unclear whether "virus envelopes" of line 2 refers to the viral cores derived from MLV in line 1 or whether it is derived from HIV or SIV or whether it can be derived from any virus. In addition, recitation of "retroviral vectors", "viral cores", and "virus

envelopes", and "envelope [and transmembrane] proteins" in the plural form renders claim 1 indefinite since it implies retroviral vectors that can accommodate multiple viral cores. Changing the claim to "A retroviral vector comprising a viral core...and a virus envelope" etc. Moreover, it unclear whether the "transmembrane proteins" of line 2 are "derived from" virus envelopes or not. Additionally, use of the term "derived from" in lines 1 and 3 renders the claim indefinite since it is unclear how "derived from" is defined or what the structural relationship is between the viruses and either the viral cores or the transmembrane proteins.

Claim 1 recites the limitation "the full-length surface envelope protein" in line 4. There is insufficient antecedent basis for this limitation in the claim. Also, it is unclear which "envelope protein" the "truncated variant" refers to.

Claim 2 is indefinite because it is unclear which viral envelopes or what part(s) of said viral envelopes are being referred to. Additionally, use of the term "derived from" in lines 1 and 2 renders the claim indefinite since it is unclear how "derived from" is defined or what the structural relationship is between the viruses and the viral envelopes.

Claim 3 is indefinite because it is unclear which viral envelopes or what part(s) of said viral envelopes are being referred to. The claim is further rendered indefinite by its recitation "which is elongated by the C-terminus" since it is unclear: (1) to what envelope protein "which" is directed; (2) what "C-terminus" (of what?) is directed to; and (3) how "retrovirus" (line 5) relates to "elongated" or "fragment".

Claims 4 and 5 are indefinite for failing to recite method steps that clearly relate back their respective preambles which recite a "[m]ethod for the preparation of packaging cells, which [or "that" in cl. 5] produce vectors according to claim 1". Claim 1 recites "viral cores derived from...MLV"; the method steps of claims 4 and 5 do not, but rather suggest additional non-MLV gag-pol-based packaging cell embodiments. Moreover, the parenthetical description applied to "packaging cell" in lines 2 and 3 of claim 4 is unclear in reciting whether the packaging cell is transfected by one or more or the "expression genes" and/or the "expression construct" in one or more transfection/selection steps or whether the "packaging cell" is already stably transformed with gag/pol etc. prior to the transfection (stable or transient?) with the envelope-expressing construct(s). In addition, it is unclear what specific type of packaging cells have in fact been created or how it they are to be used to "produce retroviral vectors according to claim 1".

Claim 4 is further rendered indefinite by its recitation of "expression-gene" (line 4) and "envelope proteins" since it is whether the "transfection" step of line 2 relates to *one* envelope protein of either HIV or SIV or whether it relates to *one or more* envelope protein of HIV *and/or* SIV. Additionally, claim 4 is indefinite in its recitation: "that produces or does not produce env-negative MLV-derived envelope proteins" since a packaging cell "that produces" cannot *produce* MLV-derived envelope proteins that are env-negative. Also, "MLV-derived" renders the claim indefinite since it is unclear how "MLV-derived" is defined or what the structural relationship is between the MLV and the envelope proteins recited. If the claim is intended to recite a packaging cells that can *alternatively* comprise "MLV-derived envelope proteins", it would be better to

leave out the part: "produces or does not produce..." since this part does not further limit the claim, but rather adds confusion instead.

Claim 4 recites the limitation "a packaging cell" in line 2. There is insufficient antecedent basis for this limitation in the claim. The method recites "preparation of packaging cells" (plural), the method step recites transfection of "a packaging cell" (singular).

Claim 5 is rendered indefinite by its recitation "the genetic information desired to be transferred" since this phrase embraces the packaging signal of line 3. Changing the phrase "and the genetic information desired to be transferred" to --,a transgene--. The phrase "and with an expression gene that contains genetic information for envelope proteins of HIV or SIV" renders claim 5 indefinite since it is unclear in what way the "genetic information" is "for envelope proteins" (e.g. coding sequences, regulatory sequences etc.). Changing the phrase to --and a transcriptional cassette encoding envelope proteins of HIV or SIV" would obviate the problem.

Claim 6 recites the limitations "the cell line TELCeB6 " in line 1. There is insufficient antecedent basis for these limitations in the claim.

Claim 7 is rendered indefinite by its recitation of "or" in line 1, since it raises questions concerning the meaning of the multiple terms in between the two "or[s]" in this context. Deleting the first "or" would probably obviate the problem.

Claim 8 is an incomplete claim since it is not clear whether the "[p]ackaging cells" are actually --obtained-- by the method of claim 4 or which "packaging cell" of claim 4 is meant.

Claim 4 recites transfection of a "packaging cell" (line 2), so presumably there is already a packaging cell near the start of the method step that is "obtainable".

Claims 9-12 provide for the use of retroviral vectors, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, and 9-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application discloses cell lines (TELCeB6) and expression plasmids (pLβAc/env-Tr712-neo and pMB2) that are encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

The specification does not teach how to reproducibly construct these biological materials from starting materials known and readily available to the public and it is unclear whether this biological material is readily available to the public. Without the expression plasmid pMB2, for example, one could not use the teachings of the specification to make envelope variants, pRep *Δ16 env*, pRep *Δ7 env*, pRep *Δ0 env*, pRep *Δ7MLV env*, and pRep *Δ0MLV env* materials. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that

the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Although claims 9-12 recite non-statutory embodiments not subject to examination, to the extent that the claims are amended to recite pharmaceutical vector compositions or their use in methods for in vivo administration to patients in need thereof, the claims read on gene therapy which are not enabled by the present disclosure.

The factors to be considered in determining enablement are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation....Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Factors that can be used in evaluating undue experimentation include: the quantity of experimentation necessary, the amount or direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Nature of the invention and state of the prior art. At the time the instant application was filed, successful use of gene therapy was not routinely obtainable by those skilled in the art. W. French Anderson, one skilled in the art, recently concluded: "[e]xcept for anecdotal reports of individual patients being helped, there is still no conclusive evidence that a gene-therapy protocol has been successful in the treatment of a human diseases [Nature, vol. 392:(Supp.), 1998, p. 25, first paragraph]...[s]everal major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered. The reason for the low efficiency of gene transfer and expression in human patients is that we still lack a basic understanding of how vectors should be constructed, what regulatory sequences are appropriate for which cell types, how in vivo immune defenses can be overcome, and how to manufacture efficiently the vectors that we do make" (p. 30, next to last paragraph). Concurring with Anderson, Verma and Somia state that "[t]he Achilles heel of gene therapy is gene delivery...and [t]hus far, the problem has been an inability to deliver genes efficiently and to obtain sustained expression" (Nature, vol. 389, 1997, p. 239, col. 3, 2nd paragraph)...[a]lthough more than 200 clinical trials are currently underway worldwide, with hundreds of patients enrolled, there is still no single outcome that we can point to as a success story" (p. 239, col. 1, 2nd paragraph).

The specification does not address the problems discussed above and it does not provide an adequate written description teaching one of ordinary skill in the art how to make and use the claimed invention to treat any disease using gene therapy.

Predictability of the art. The physiological art is recognized as unpredictable (MPEP 2164.03). As set forth in *In re Fisher,* 166 USPQ 18 (CCPA 1970), compliance with 35 USC 112, first paragraph requires:

> that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.

Gene therapy is inherently unpredictable since it involves introduction of artificially created compositions into a highly complex milieu presenting a multitude of counteracting forces.

Guidance and working examples. The specification provides little or no guidance teaching one of ordinary skill in the art how to make or use the retroviral vectors recited for treatment of any disease by gene therapy. No working examples have been provided.

Amount of experimentation necessary. Given the unpredictable and undeveloped state of the art as described above, it would likely require considerable experimentation to appropriately develop the claimed method for treating any disease by gene therapy.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods. This is particularly true given the state of the art, the nature of the invention, the unpredictability of the art, the scarcity of guidance and working examples in the specification, and the amount of experimentation necessary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Schnierle et al., (Proc. Natl. Acad. Sci. USA, 94:8640-8645, 1997).

Schnierle et al. disclose the pseudotyping of a MLV "expression construct", MFG-*nlslacZ*, using stable clones of the MLV env-negative packaging cell line TELCeB6 expressing the truncated envelope gene pTr712 from pLβAc/env-Tr712-neo (see p. 8640, abstract; p. 8641, left column, 2nd paragraph; p. 8641, right column, first paragraph of RESULTS; and p. 8643, left column, 2nd full paragraph).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Schnierle et al. (Proc. Natl. Acad. Sci. USA, 94:8640-8645, 1997) disclose the invention of claims 1-8 as described in the above 35 U.S.C. 102(a) rejection above. At the bottom right of p. 8640, the prior art reference states that "B. S. S. [Barbara S. Schnierle] and J. S. [Jorn Stitz] contributed equally to this work". However, Barbara S. Schnierle, who contributed as equally to the work disclosing the claimed subject matter of the present invention as Jorn Stitz, a co-inventor along with Klaus Cichutek, is not a listed co-inventor of the instant application. Therefore, the evidence of record indicates that the co-inventors named on this application are not the sole inventors of the claimed subject matter.

Claims 1-5 and 8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Mammano et al. (J. Virol., 71:3341-3345, 1997).

Mammano et al. disclose the production of Mo-MLV particles pseudotyped with a truncated HIV envelope protein (i.e. transmembrane glycoprotein, gp41; see abstract and p. 3341, right column, lines 10-14) following triple-transfection of a packaging cell line (293T) with a Mo-MLV Gag-Pol expression construct (p*gag-pol*gpt), a transgene-containing "expression construct" or transducing/packaging construct, and a C-terminally truncated HIV-1 Env expression construct (see p. 3343, left column and Table 1).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Parolin et al.(J. Virol., 68:3888-3895, 1994).

Parolin et al. disclose triple-transfection of a packaging cell (COS-1, expressing SV40 T antigen) with "expression genes" encoding HIV-1 gag and pol (via CMVΔP1ΔenvpA plasmid), along with an "an expression construct, comprising a packaging signal (psi) and the genetic information desired to be transferred" (e.g. v653 RSN, for example; see p. 3892, left column) and "an expression gene that contains the genetic information for envelope proteins of HIV or SIV" (pSVIIIenv3-2; refer to cl. 4). It is noted that the claims do not specifically recite method steps comprising transfection of "packaging cells" (cl. 4) or "a cell" (cl. 5) comprising MLV "viral cores" with MLV-encoded gag and pol proteins (see also 35 U.S.C. 112 2nd rejection above).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denesvre et al. (J. Virol., 70:4380-4386, 1996) in view of Salmons et al. (Leukemia, 9(Suppl.):S53-S60, 1995) and either Wilk et al. (Virology, 189:167-177, 1992) or Zingler et al. (J. Virol. 67:2824-2831, 1993).

Denesvre et al. discloses a series of transmembrane domain (TM) swapping experiments involving expression of complete, truncated, or chimeric (including cytoplasmic tail substitutions analgous to pRep *Δ7MLV env*, and pRep *Δ0MLV env*, for example) HTLV-1 env and F-MuLV (i.e. F-MLV) envelopes in a packaging cell line expressing Mo-MLV (i.e. MLV) gag/pol cores (e.g. TELCeB6) that can be used to generate pseudotypic virus particles and/or packaging and producer cell lines following transfection with heterologous envelope "expression genes" and psi-containing "expression constructs". Their results were interpreted to suggest a simple rule to apply wherein retroviral cores allow incorporation of heterologous envelopes (such as those of HIV or SIV) whose cytoplasmic tails are smaller than that of the original parental envelope (i.e. MLV; p. 4385, left column last paragraph). They further draw attention to the negative effect of the HIV env cytoplasmic tail (p. 4380, right column; p. 4385, bottom of left column, and references 12, and 24 therein) and further suggest that the cytoplasmic tail in the HIV envelope may be responsible for an exclusion process from heterologous MuLV (i.e. MLV) particles. Moreover, Denesvre et al. disclose that full-length cytoplasmic tails of HTLV-1 and F-MuMLV

were reproducibly more cytotoxic toward TELCeB6 cells. Denesvre et al. do not specifically disclose MLV/HIV or MLV/SIV pseudotype retroviral vectors nor do they disclose packaging and/or producer cell lines which produce these vectors.

Salmons et al. discloses that the envelope protein of human immunodeficiency virus, which principally infects cells expressing the CD4 receptor, could be used to target expression of MLV based retroviruses to this cell type through engineering of a MLV/HIV pseudotype (see p. S58, left column, 1st full paragraph).

Wilk et al. discloses HIV envelope mutants (including Tr712) with C-terminal truncations that retain the ability to incorporate itself into virus particles and be infectious and further exhibits a CD4-dependent fusion capacity double that of the wild-type envelope .

Zingler et al. discloses SIV envelope mutants with C-terminal truncations exhibiting enhanced CD4-dependent infectivity, fusogenicity, and incorporation into viral particles.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the teachings of heterologous envelope C-terminal truncation and/or substitution mutants and use of the MLV retroviral core cell lines of Denesvre et al. (incl. TELCeBe6) to make the MLV/HIV pseudotypes of Salmons et al. using the truncated HIV envelopes of Wilk et al.or the truncated SIV envelopes of Zingler et al. as well as the accompanying packaging and/or producer cell lines resulting therefrom. One of ordinary skill in the art would have would motivated to utilize the envelope truncation mutants in view of their capacity to promote enhanced heterologous viral particle incorporation, infectivity and

fusogenicity, and their established utility for generating MLV pseudotypes, combined with the accompanying predictions for making such pseudotypes as taught by Denesvre et al, and would therefore have predicted a reasonable expectation of success. Thus, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, Ph.D. can be reached at (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Peter Brunovskis, Ph.D.
Patent Examiner
Art Unit 1632
February 29, 2000

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.